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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,836	03/30/2006	Angelo Guglielmotti	281760US0PCT	6824

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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RAMACHANDRAN, UMAMAHESWARI

ART UNIT	PAPER NUMBER
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1627

NOTIFICATION DATE	DELIVERY MODE
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08/02/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/560,836	<b>Applicant(s)</b> GUGLIELMOTTI ET AL.	
	<b>Examiner</b> UMAMAHESWARI RAMACHANDRAN	<b>Art Unit</b> 1627	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-12 and 14-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The Board's decision of 5/25/2010 is acknowledged herewith. In view of the Board's decision of affirming the rejection of claims 20-23 under 35 USC 103(a) as being unpatentable over Gaster, Smith, Jorum and Omoigui and reversing the rejection of claims 6-12 and 14-17 under 35 USC 103(a) as being unpatentable over Gaster, Smith and Jorum and also reversing the rejection of claims 18-20 under 35 USC 103(a) as being unpatentable over Gaster, Smith, Jorum and Wickenden prosecution is hereby reopened. In view of the Board's rationale for relying on the Omoigui reference in the affirmance of the rejection of claims 20-23 examiner has decided to reopen prosecution.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Technology Center Director has approved of reopening prosecution by signing below:

Claims 6-12, 14-23 are pending and are being examined on the merits herein.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-12, 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omoigui (US 2004/0038874, effective filing date Aug 22 2002) in view of Gaster et al (EP 0630736) and Smith et al. (Neuroscience Letters, 271, 1999, 61-64).

Omoigui's teachings disclose a method for treating persistent pain by inhibiting mediators of inflammation including serotonin. (Omoigui, Abstract). Omoigui teaches that "antagonism of inflammation and the inflammatory response will relieve pain of every origin, type and character." (para [0004]). Omoigui further teaches that "the hallmarks of neuropathic pain are chronic allodynia and hyperalgesia." (para [0072]). Embodiments of Omoigui's method includes treating "neuropathic pain syndrome

Art Unit: 1627

including neuralgia or nerve pain, carpal tunnel syndrome, post herpetic neuralgia" (p 11, claim 12), and administering a serotonin receptor antagonist (p 13, claim 80). The reference further teaches that serotonin receptor antagonist is administered intramuscularly, intravenously, subcutaneously, orally or rectally (p 13, claim 84).

The reference Omoigui do not teach the claimed compounds in a method of treating neuropathic pain.

Gaster et al. teaches the compounds of formula I (claim 1) to be 5-HT<sub>4</sub>, serotonin receptor antagonists (p1 lines 6-8) and further teaches a method of treatment of irritable bowel syndrome, migraine etc in mammals (p6, lines 42-43) comprising administering these compounds.

Smith teaches a method comprising a combination administration of a 5-HT<sub>4</sub> antagonist (SB 207266) and a 5-HT<sub>3</sub> antagonist resulted in inhibition of intestinal allodynia (see abstract, p 63, and lines 3-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the compounds of formula I in the treatment of neuropathic pain based on the teachings of Omoigui and Gaster. Omoigui explicitly teaches treating neuropathic pain with a serotonin receptor antagonist (p11, claim 12, p 13, claim 80). Gaster teaches the compounds of formula I to be 5-HT<sub>4</sub>, serotonin receptor 4 antagonists. It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered Gaster's serotonin receptor 4-antagonist compounds to treat neuropathic pain in the method of Omoigui in expectation of similar or better therapeutic benefits. A person of ordinary skill in the art at the time of the invention

Art Unit: 1627

would have been motivated in using Gaster's serotonin receptor antagonist compounds for Omoigui's serotonin receptor antagonist in a method of treating neuropathic with a reasonable expectation of success because Omoigui explicitly teaches treating neuropathic pain with a serotonin receptor antagonist. Omoigui teaches that the hallmarks of neuropathic pain are chronic allodynia and hyperalgesia. Omoigui teaches neuropathic pain can be treated in general with all types of serotonin receptor antagonists which includes serotonin type 4 antagonists. Smith teaches that a method comprising administering a 5-HT4 antagonist inhibited intestinal allodynia. The instant claims are towards a method of treating neuropathic pain comprising administering compounds of formula I which has been taught by Gaster to be serotonin receptor 4 antagonists. The transitional term 'comprising' is inclusive or open and does not exclude additional unrecited elements or method steps. Hence from Omoigui's and Smith's teachings it would have been obvious to a person of ordinary skill in the art to choose a serotonin receptor antagonist, specifically a 5HT-4 antagonist such as Gaster's compounds in a method of treating neuropathic pain or allodynia, a clinical finding in neuropathic pain.

It would have been obvious to a person of ordinary skill in the art at the time of the invention from the teachings of Omoigui that allodynia and hyperalgesia are hallmarks of neuropathic pain. Hence a subject suffering from neuropathic pain as claimed (claims 16, 17) would have allodynia and/or hyperalgesia as frequent symptoms of the neuropathic pain disease.

Art Unit: 1627

It would have been obvious to a person of ordinary skill in the art, at the time of invention to have used Gaster's compound in a method of treatment to a subject who has neuropathic pain, irrespective of whether the pain is induced either as a result of cancer or diabetes or otherwise (claims 18, 19) because Omoigui teaches that persistent pain disorders including neuropathic pain can be treated by serotonin receptor antagonist. Neuropathic pain is a symptom associated with many diseases and the cause of the pain or the diseases associated with the pain is irrelevant if neuropathic pain can be treated by administration of a drug. Thus as the prior art teaches treating neuropathic pain, pain associated with any disorder, including diabetes or cancer will be treatable by administration of Gaster's serotonin receptor antagonist compounds.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UMAMAHESWARI RAMACHANDRAN whose telephone number is (571)272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1627

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/  
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Director, Technology Center 1600